

REMARKS/ARGUMENTS

Favorable reconsideration of this application, as presently amended, is respectfully requested.

Claim 20 has been amended to clarify that the “tap” is “selectively openable ... to control entry and exit of air through the first cannula.” Basis for this is found at lines 11-13 of page 3, and in the description of the opening and closing of the tap at line 28 of page 7 and line 2 of page 8.

As was explained in the last response, in order to permit operation of a disposable container under sterile conditions in any environment and devoid of sterile hoods, the top end of the container comprises a removable lid provided with a first cannula having a removable stopper and a tap, as well as a second cannula that can be accessed by a hollow needle, through a pierceable membrane, to transfer a fluid biological material into or from the container, and a third cannula operationally connected to an attachment configured to receive and accommodate one end of a syringe to transfer a fluid biological material into or from the container.

The claims have again been rejected under 35 U.S.C. § 103 as being obvious over Smith et al in view of Vlasselaer. According to this rejection, (1) the term “tap” in Claim 20 was broad enough to read on the filter 84 of the entry port 82 shown in Fig. 6 of Vlasselaer, and (2) the description of a “sterile septum” as the fitting 80 in Vlasselaer (col. 11, lines 25-32) inherently discloses a membrane, rendering the use of such a membrane in Smith et al to be obvious.

As to the first of the above points, Claim 20 has been amended to further recite that the tap is “selectively openable ... to control entry and exit of air through the first cannula.” A filter is not a “selectively openable” element that is capable of controlling the entry and exit of air; a filter removes particles from a gas passing therethrough but does not control

such passage. Accordingly, the filter 84 of Vlasselaer is not “selectively openable ... to control entry and exit of air” and cannot teach the presently claimed tap for inclusion in Smith et al.

Moreover, one skilled in the art would not have been motivated to have replaced the vent hole 42 in the lid of Smith et al with a cannula including a selectively openable tap capable of controlling the entry and exit of air. Smith et al provides a simple vent hole 42 to maintain a “neutral pressure” within the receptacle 12 (paragraph [0031]). Maintaining “neutral pressure” requires the free flow of air through the vent hole to equalize inside and outside pressures. The action of a “selectively openable” tap could only detract from such a desired “neutral pressure” and would not be included in Smith et al.

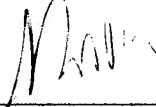
As to the second point, Vlasselaer does not teach a pierceable membrane in a second cannula, either explicitly or inherently, and so could not have suggested the same for inclusion in Smith et al. The description of a “sterile septum” at column 11 in Vlasselaer does not inherently describe a membrane because a septum need not be a membrane. Indeed, col. 3 of Vlasselaer further describes that the “sterile septum” is “a SAFSITE™ small wire extension set with reflux valve and Spin-Lock™ adaptor available from Burrion Medical Inc., Bethlehem, Pa.” The SAFSITE™ small wire extension set is not a membrane, but a two-way reflux valve.¹ Since Vlasselaer does not teach a pierceable membrane in a second cannula, it could not suggest the same for inclusion in the cannulae of Smith et al.

¹ See <http://bbraunusa.com/index-09874C43D0B759A1E306854FD0DACB42.html>.

Applicant therefore believes that the present application is in a condition for allowance and respectfully solicits an early notice of allowability.

Respectfully submitted,

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